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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,411

Applicant(s)

FESTO, NORBERTO

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,9,13-15,18-43 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-38,41,42 and 58 is/are allowed.
- 6) ☒ Claim(s) 22 and 24 is/are rejected.
- 7) ☒ Claim(s) 1, 3-4, 9, 13-15, 18-21, 23, 25-30, 39, 40, and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Final Rejection

The Status of Claims:

Claims 1, 3-4, 9, 13-15, 18-43, and 58 are pending.

Claims 22, and 24 have been rejected.

Claims 1, 3-4, 9, 13-15, 18-21, 23, 25-30, 39, 40, and 43 have been objected.

Claims 31-38, 41-42, and 58 are allowable.

Claim Objections

In claim 1, the phrase “apart from” is recited. There is no gap between the word “a” and the word “part”. Therefore, an appropriate correction is required.

In claim 9, it depends on claim 13, This is improper because claim 9 should be dependent on the claim prior to claim 9. Therefore, an appropriate correction is required.

In claim 43, the phrase “wherein is 0.01 % to 10 % by weight of the pharmaceutical composition” is recited. There is no subject in the sentence. Therefore, an appropriate correction is required.

Claims 3-4, 13-15, 18-21, 23, 25-30, 39, and 40 have been objected due to the objected claim 1.

Claim Rejections - 35 USC § 112

1. Applicants’ argument filed 9/27/04 have been fully considered but are not persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 14, 29-30, 33, 36, and 39-57 under 35 U.S.C. 112, second paragraph has been withdrawn due to the modification made in the amendment .

However, there are still some issues to be resolved with claims 22 and 24.

In claim 22, the phrase “ an antineoplastic adjunct including folic replenishers” is recited. This is vague and indefinite because the word “including” would mean that there are some additional components besides folic replenishers. Therefore, an appropriate correction is required.

In claim 24 , the phrase “ the active ingredient comprises” is recited. This is vague and indefinite because the word “comprises” would mean that there are some additional components besides the active ingredient. Therefore, an appropriate correction is required.

Applicants argue the following issues:

- a. Since claims 14, 22, 24, 25-26, 29-30, 33, 36 , 39-43, and 58 have been amended, and claims 44-57 have been deleted in response to the Office Action, the application is now in condition for allowance.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the argument , the Examiner has noted applicants' arguments. However, there are still some issues to be resolved with the objection of claims 1, 9, and 43 and the rejected claims 22 and 24. Until the issues are resolved , the allowance of the application will be delayed.

Conclusion

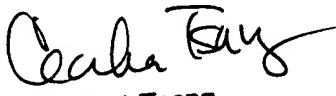
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

*** Taylor Victor Oh
4/2/05


Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600